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Health Care Utilizing Behavioral Activation for Depression

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14. ABSTRACT In-home care offers the potential of greatly increasing access that Service members and Veterans have to behavioral health services. This study directly compares In-Home care delivery to Face-to-face treatment using a randomized, non-inferiority trial design. While both treatment conditions resulted in important clinical gains, the non-inferiority of in-home care cannot be determined by the results of this trial alone.					
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## Table of Contents

	<u>Page</u>
Introduction.....	4
Body.....	4
Key Research Accomplishments.....	5
Reportable Outcomes.....	6
Conclusion.....	7
References.....	7
Appendices.....	8

## INTRODUCTION

In-home tele-behavioral health treatments have the potential to address current health needs of Service Members, Veterans, and their families, especially for those that live in rural and underserved areas. The use of in-home, web-based video-conferencing treatment to address the psychological needs of Service Members and Veterans is not yet considered standard of care for the DoD. The safety and clinical efficacy of such treatments must be established before broad dissemination of these treatment programs occurs. This study is a two-group (web-based in-home BA vs. in-person BA) prospective randomized controlled trial. Both groups were assessed at baseline, mid-treatment (Week 4), post-treatment (Week 8), and at a 3-month follow-up visit. The primary outcome variables include safety and hopelessness. Secondary outcome variables include depression, anxiety, PTSD symptoms, attitudes toward seeking mental health services, quality of life, and health care utilization, as well as treatment satisfaction, adherence, and compliance. 121 participants were recruited. Participants were Regular Service Members, National Guard Members, Reservists, and Veterans recruited at Madigan Army Medical Center and the Portland VA Medical Center.

## BODY

The protocol was reviewed by The Human Research Protection Office (HRPO) and initial approval was granted on 30 April 2012. The Portland VA site received HRPO approval on 26 September 2012. Currently, both sites have ended recruitment, and study participation has ended for all participants. Continuing review of this protocol, an annual requirement, was completed and approved by the Madigan IRB on 08 Oct 2014 with an expiration date of 21 Oct 2015.

Completion of the recruitment, treatment, and follow-up phases of the study were our main goals over the past year. Conducting the primary, clinically focused data analysis was also a priority. Combined across both sites, 158 participants were consented to participate and completed intake interviews. Of those, 121 were eligible for randomization, while 37 failed to meet inclusion criteria. Currently, all participant interactions are complete, and a description of participant flow through the study can be reviewed in Appendix A.

In the past year, the manuscript detailing the PTSD Pilot Study associated with the larger RCT has been successfully accepted for publication in the journal *Telemedicine and eHealth*. The final report for this project was submitted to the IRB in October 2014, and study closure was approved on 16 Jan 14.

During the period covered by this review, the Madigan Healthcare System IRB approved two specific modifications to this project's research protocol. The first, approved 10 Jun 2014, increased the total number of individuals who could be enrolled for treatment at the JBLM site from 90 to 100. The second, approved 13 Nov 2014, simply provided an update to our data analysis plan. Additionally, the study was reviewed by the Medical Monitor, Dr. Karstin Slade, on 9/17/2014.

## Challenges

An important use of the data generated by this trial is the examination of economic costs/savings of home-based care. Finding the right group of health economic experts to conduct the appropriate analyses has been challenging, but we feel that we have now identified a productive and skilled research group at the University of Washington's Department of Pharmacy who is

capable of completing this sophisticated analysis. The NCE period will be used to complete this process.

## **KEY RESEARCH ACCOMPLISHMENTS**

### *Administrative and Logistical Matters*

1. Personnel
  - a. The Geneva contract at T2 is fully staffed, in accordance with the budget and planning documents for the current NCE period with no additional plans to hire.
  - b. The Portland VA site of the study went through a planned close-down, which went into effect on 27 Feb 2015. All of their staff have completed their study duties and properly closed the project with their IRB and other regulatory bodies.
2. Equipment
  - a. All study equipment used by participants has been returned and accounted for. All study equipment is currently secured at the JBLM site. MOVI/Jabber licenses obtained for this study are still active, but due to lack of use (since the treatment phase is complete), the licensing agreements will soon expire.
3. Materials, supplies and consumables
  - a. Materials required for study close out procedures (archiving records and storing equipment) have been ordered and used.
4. Institutional Review Board (IRB)
  - a. In-Home Depression RCT
    - i. Madigan IRB approves protocol modification on 10 Jun 2014.
    - ii. Medical Monitor reviews study procedures on 17 Sept 2014.
    - iii. Madigan IRB completed Continuing Review on 08 Oct 2014.
    - iv. Madigan IRB approves protocol modification on 13 Jan 2015.
  - b. In-Home PTSD Pilot
    - i. Madigan IRB approves pilot study closure on 16 Oct 2014.

## **REPORTABLE OUTCOMES**

*Beck Depression Inventory (BDI) and Beck Hopelessness Scale (BHS)* - For the primary hypothesis of non-inferiority in terms of safety, the Beck Hopelessness Scale was used as the primary measure. Based on the analyses, we cannot reject a null hypothesis of inferiority of in-home telehealth as compared to in-office therapy. For the other hypothesis relating to non-inferiority of treatment efficacy for depression, we cannot reject the null hypothesis of inferiority of in-home telehealth as compared to in-office treatment.

Because the range of the confidence intervals around the observed values of the BDI and BHS extend beyond both “0” and the non-inferiority threshold, the appropriate statistical conclusion is that the results from this project are inconclusive and that we cannot determine whether in-home treatment is- or is not- any worse than face-to-face treatment in cases of depression.

However, based on the data, the outcomes suggest that both in-person and in-home implementations of behavioral activation for depression resulted in decreases in both hopelessness, as measured by the BHS, and depression, as measured by the BDI. Additionally, the effective management of patients in crisis was both feasible and effective when treatment was being provided remotely.

*Beck Anxiety Inventory* – Differences between the in-home and face-to-face groups suggested that the in-home group had higher BAI scores at all time-points post randomization. The non-inferiority analysis of the BAI indicated that the standardized difference of 0.30 at post treatment and its upper bound of the 90% confidence interval of 0.58 exceeded the margin on 0.50.

*PTSD Checklist-Military* – Similar to the other measures, the point estimates at the measurement times post randomization indicated that the in-home participants had higher scores than the face-to-face participants. The upper bound of the standardized 90% confidence intervals was below 0.50 at post treatment which would allow us to reject a null hypothesis of inferiority if such a hypothesis were made and was considered reasonable given the subject pool and behavioral outcome addressed in the treatment.

*Inventory of Attitudes toward Seeking Mental Health Services* – Attitudes toward seeking health were slightly higher for the in-home group at post treatment and follow-up based on the point estimates. Standardized differences were small in magnitude and the upper bound of the 90% confidence interval at post treatment excludes 0.50.

*Client Satisfaction Questionnaire* – The valence of this measure is such that higher scores indicate higher satisfaction. At post treatment, the in-home participants had a lower average score on satisfaction compared to the face-to-face participants per the point estimate. The upper 90% confidence interval of this difference, once standardized, excluded 0.50.

**The following manuscripts related to these projects have been completed over the past year:**

Luxton, D.D., Pruitt, L.D., O'Brien, K., & Kramer, G. (2015). An evaluation of the feasibility and safety of a home-based telemental health treatment for PTSD in the US military. *Telemedicine and eHealth*.

Jenkins-Guarnieri, M., Pruitt, L. D., Luxton, D. D., Johnson, K. (2015). Patient Perceptions of Telemental Health: Systematic Review of Direct Comparisons to In-Person Psychotherapeutic Treatments. *Telemedicine and eHealth*.

Luxton, D.D., O'Brien, K., Pruitt, L.D., Kramer, G., Johnson, K. (2014). Suicide risk management during clinical telepractice. *International Journal of Psychiatry in Medicine*, 48, 19-31. doi: <http://dx.doi.org/10.2190/PM.48.1.c>

Luxton, D.D., Pruitt, L.D., O'Brien, K., Stanfill, K., Jenkins-Guarnieri, M.A., Johnson, K., et al. (2014). Design and methodology of a randomized clinical trial of home-based telemental health

treatment for U.S. military personnel and veterans with depression. *Contemporary Clinical Trials*, 38, 134-144. doi: 10.1016/j.cct.2014.04.002

## **CONCLUSION**

Both in-office and in-home treatment delivery produced a meaningful clinical effect. The results are inconclusive, however, regarding the equivalency of In-home treatment compared to in-person treatment. The overall safety of delivering care to the homes of Service Members and veterans is supported, as are the effects of Behavioral Activation as a treatment for depression.

## **REFERENCES**

None

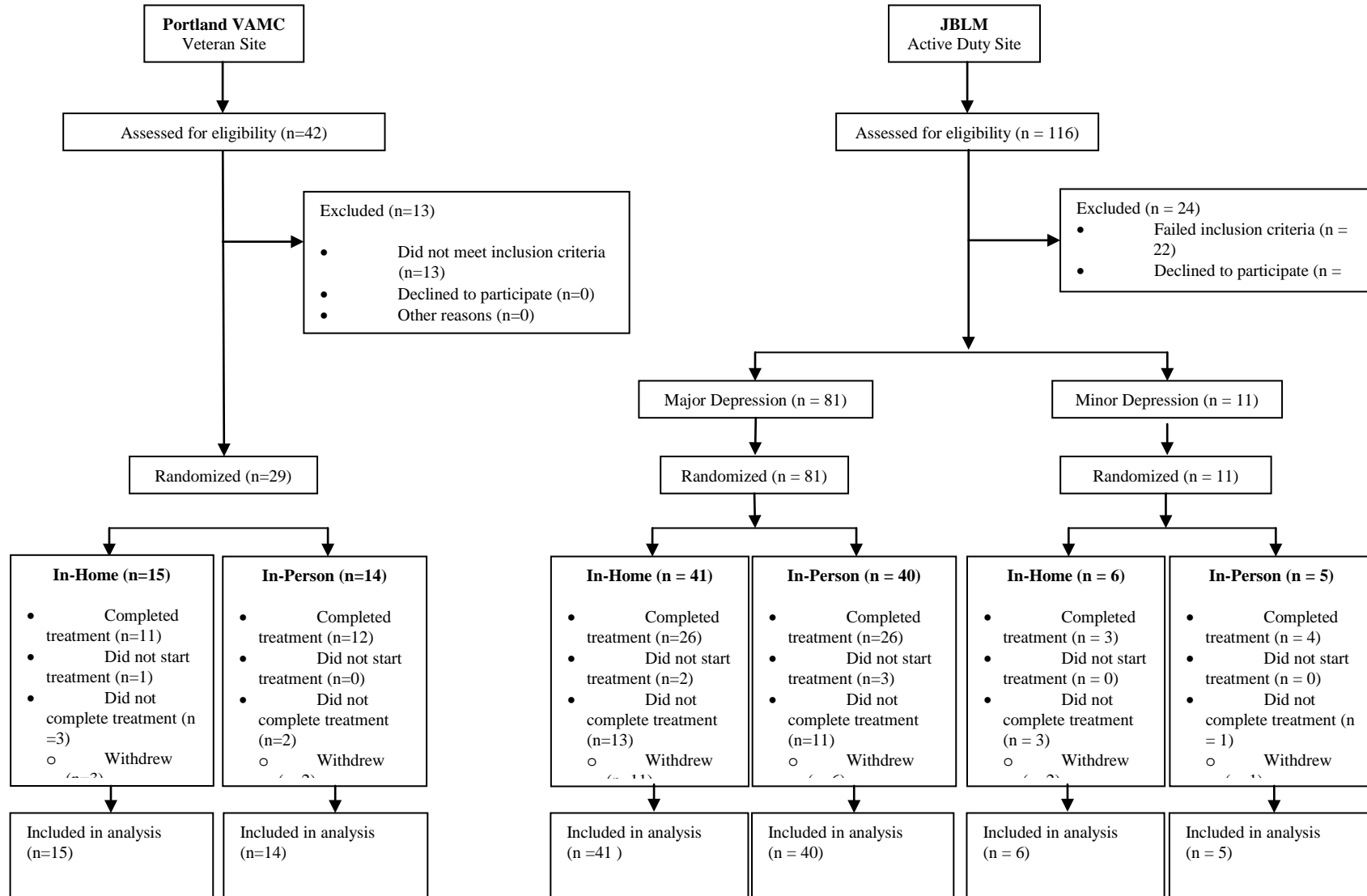
## **APPENDICIES**

Appendix A: Consort Diagram.

Appendix B: Suicide risk management during clinical telepractice.

Appendix C: Design and methodology of a randomized clinical trial of home-based telemental health treatment for U.S. military personnel and veterans with depression.

## Appendix A: Consort Diagram





## **SUICIDE RISK MANAGEMENT DURING CLINICAL TELEPRACTICE\***

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### **ABSTRACT**

The effective assessment and management of suicidal patients is an essential component of telehealth-based care. With this article, we describe how we have implemented procedures for the ongoing assessment and management of suicide risk in a clinical trial that compares in-office treatment to home-based treatment delivered via web-cam to U.S. military service members and veterans with depression. We describe our safety protocol and how it was adapted from current recommended best practices, published guidelines, and local requirements for managing patient safety during home-based telepractice. We conclude with discussion of other key safety issues associated with telepractice. The topics discussed are relevant to all mental health practitioners who are interested in clinical telepractice services.

*(Int'l. J. Psychiatry in Medicine 2014;48:19-31)*

**Key Words:** suicide risk, patient safety, risk management, telehealth, telemedicine

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## INTRODUCTION

The effective assessment and management of suicidal patients is a critical component of both conventional in-office care and telehealth-based care. There are aspects of telepractice, however, that require additional considerations for managing the safety of patients who are or become high risk for suicidal behavior while under care. In clinically supervised settings (e.g., a provider's office, clinics, hospitals, etc.), clinical staff are typically available to assist during a clinical crisis by coordinating emergency services, providing consultation, or escorting a patient to the emergency department. The same is not necessarily true when care is delivered to settings that do not have clinical supervision at the remote site (e.g., a patient's home). Thus, management of suicide risk and patient safety during telepractice involves additional considerations and requirements. A particular concern is what to do in situations where a patient expresses intent to harm him/herself at the end of a telehealth session or before unexpectedly disconnecting from the session [1]. In order to effectively manage this type of crisis or other emergency situations (e.g., medical emergencies), it is necessary for telehealth providers to have a pre-planned process in place.

The assessment and management of patients' suicidal behavior while under care can be a very difficult and stressful experience for mental health clinicians [2, 3]. In the case of clinical telepractice, stress and anxiety can be exacerbated by the fear of having less control of the situation, unfamiliarity with safety procedures, technology issues, and concerns about liability [1]. The issue of potential liability is of particular concern for many mental health practitioners because inadequate suicide risk management can result in licensure complaints and/or malpractice lawsuits. Due to the ethical and legal responsibilities mental health practitioners have toward patients, liability can occur from even the briefest of patient contacts. The use of technology to deliver care (e.g., video conferencing, e-mail, web chat) introduces additional ways that a professional relationship can form and with it raises responsibilities to assess and manage suicide risk. The anxiety and concern about liability issues among individual practitioners and healthcare organizations as a result of these additional methods of delivering care can present a barrier to the wider adoption of telehealth-based services.

Several organizations, such as the American Psychological Association (APA) and the American Telemedicine Association (ATA) have issued guidelines that include provisions for patient safety management during telepractice [4, 5]. The American Psychiatric Association does not have its own telepractice guidebook, although the association refers its constituents interested in telemedicine to the ATA guidelines [6]. Clinical best practices regarding safety management specific to telemental health have also been published [7, 8], as have telemental health guidebooks that address patient safety [9]. Although the available guidelines, extant telepractice literature, and the general suicide risk management literature [2, 10-14] provide frameworks for effective risk management, the

literature is limited in detailed information regarding real-world implementation of suicide risk assessment and management protocols for telehealth-based services, particularly to clinically unsupervised settings such as the home.

With this article we address this limitation by describing how we have translated safety guidelines, practice recommendations, and local requirements into ongoing assessment and management of suicidal risk as part of a clinical trial that compares in-office treatment to care delivered to the home via web-cam to patients with depression. We describe our safety protocol, suicide risk assessment and management procedures, and how we have applied our safety protocol to mitigate risk during telepractice. We recognize that our protocol is limited by the specific clinical setting and population (clinical research at U.S. military and VA Hospitals); however, the principles and issues that we describe have applicability to other clinical telepractice settings. We do not elaborate on the issues surrounding licensure and liability as these have been adequately covered elsewhere [15].

### **CLINICAL TRIAL DESCRIPTION AND SAFETY PROCEDURES**

The clinical trial (ClinicalTrials.gov Identifier #NCT01599585) is being conducted at the U.S. Department of Defense's National Center for Telehealth and Technology (T2) located at Joint Base Lewis-McChord (JBLM) in Washington State and at the Portland VA Healthcare System in Oregon. The aim of the trial is to compare in-office to home-based delivery of an abbreviated (eight-session) version of the revised Brief Behavioral Activation for Depression protocol (BATD-R) [16]. BATD-R is a behavioral reinforcement-based treatment that has received extensive empirical support as a treatment for depression [17]. Patients in our trial include both U.S. military personnel and veterans who either self-refer or are referred to the study by behavioral health providers at each respective site. While home-based telemental health treatments are already being expanded in the VA Health System, home-based telemental healthcare is not presently the standard of care in the U.S. military. Thus, the primary purpose of the trial is to examine the feasibility, safety, and effectiveness of home-based telemental health in the military setting to inform policy for broader implementation of home-based treatments. The study protocol adheres to the principles and recommendations of the World Medical Association, Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects, as well as all applicable Codes of Federal Regulation and Department of Army Regulations. This study was approved by the Madigan Army Medical Center Institutional Review Board and the Army Human Research Protection Office.

For our trial, eligible participants are randomized to either the in-office or in-home treatment groups. All participants are provided with eight sessions of BATD that follows a treatment manual [17]. Participants in both intervention

groups follow the same assessment schedule with clinical assessments at baseline (before first treatment session), mid-treatment (week 4), 1-week post-treatment, and 3-months post-treatment. A detailed description of the trial's methodology is published elsewhere [16].

### **Safety Protocol**

The essential components of our safety protocol planning steps and processes are shown in Table 1. The safety protocol was designed in accordance with the professional guidelines and best practices literature available at the time [5, 7] and is consistent with the most recent applicable guidelines from both the American Telemedicine Association [18] and American Psychological Association [4]. Our safety protocol was made into a formal written plan that is part of our trial's research protocol.

The development of our safety protocol began with review of applicable local regulatory requirements and guidance. Our study clinicians (clinical psychologists) are credentialed providers at Federal facilities; Madigan Army Medical Center (MAMC) and Portland VA Medical Center (PVAMC). Thus, the standard operating procedures (SOP) of the Army and PVAMC were reviewed and included in our plan. This review included examination of duty-to-warn and mandated safety reporting requirements. For active-duty military personnel, their command must be notified when the service member's safety is a concern. Thus, these patients are asked to provide command contact information. The use of support persons is a recommended approach to telehealth safety planning [5, 7]. Depending on the type of clinical setting, an additional support person to assist with coordination in emergencies could include another treatment provider, other designated staff at the patient site, a family member, or a local community contact who knows the patient and agrees to remain reachable during telehealth sessions [19]. Thus, we ask patients at both sites to identify another person (e.g., family member, partner, or friend) who can be notified in case of an emergency. Patients at both sites are asked to complete a site specific release of information form so that the third party can assist in cases of emergency or imminent risk. These processes are discussed with our patients during the informed consent process upon entry into the clinical trial.

### **Screening and Assessment**

Telepractice guidelines uniformly urge clinicians to determine appropriateness of each patient for telehealth care prior to initiating services [4, 5]. "Appropriateness" varies across contexts based on several factors including technology considerations, patient needs and preferences, and administrative regulations [1, 7]. In mental health care, suicide risk assessment is a critical aspect of determining appropriateness for varied treatment modalities. In our trial, suicide risk assessment begins during the initial in-person screening of patients. We first administer

Table 1. Overarching Safety Plan Steps and Process

Safety planning step	Process
Practice within institutional rules, regulations, and state laws	<ul style="list-style-type: none"> <li>• Review local and health systems regulations.</li> <li>• Providers receive training and supervision on pertinent institutional and legal regulations for providing telehealth-based care.</li> </ul>
Determine appropriateness of telehealth-based care	<ul style="list-style-type: none"> <li>• Conduct pre-treatment clinical assessment and suicide screen to determine risks, contraindications, etc.</li> </ul>
Ensure adequacy of home-environment, technology, and devices	<ul style="list-style-type: none"> <li>• Test infrastructure for adequate bandwidth.</li> <li>• Assess quality of environment (e.g., sound, lighting, privacy, etc.) and equipment (e.g., computer, microphones, cameras, etc.).</li> <li>• Ensure tech support plan and materials (troubleshooting guides).</li> <li>• Plan for maintaining privacy at patient's end.</li> </ul>
Conduct site assessments and establish procedures	<ul style="list-style-type: none"> <li>• Obtain alternative contact numbers from patient.</li> <li>• Obtain patient's local emergency contact information and confirm with EMS agency (using non-emergency line).</li> <li>• Identify local collaborators (e.g., Patient Support Person) that can be called to support patient safety during crisis.</li> <li>• Obtain needed authorizations to release information.</li> <li>• Provider ensures that he/she has access to a secondary phone line in the clinical room during appointments.</li> <li>• Have secondary staff available during appointments to coordinate with EMS, if needed.</li> </ul>
Discuss roles and responsibilities with patient	<ul style="list-style-type: none"> <li>• Discuss technical troubleshooting with patient and have an agreed upon method for re-establishing contact during service disruption (e.g., via telephone).</li> </ul>
Evaluate patient risk during and after treatment	<ul style="list-style-type: none"> <li>• Monitor psychiatric symptom levels.</li> <li>• Assess for presence and/or change in suicidality.</li> <li>• Monitor relevant changes in patient's home environment.</li> <li>• <i>(If indicated by risk level)</i> Develop multi-step safety plan and provide patient with a copy of the plan. Lead a direct and candid discussion about patient's access to firearms or other lethal means, and generate strategies to restrict access. Determine how transportation, if necessary, will be handled and whether to utilize a local collaborator.</li> <li>• <i>(If indicated by risk level)</i> Try to remain connected to patient via VTC while coordinating involvement of EMS by telephone. Involve secondary staff and notify third parties as warranted.</li> </ul>

**Note:** This list is based on that presented by Luxton and colleagues [7].

the Structured Clinical Interview for the DSM-IV Axis I Disorders, Research Version, Patient Edition (SCID-I/P) [20] to determine initial study eligibility and to screen for current suicidal ideation and past self-injurious events. Potential patients are ineligible for the trial if they report a suicide attempt during the past 6 months or if they have current ideation with stated intent. These exclusion criteria may eliminate the highest risk patients that are encountered in other clinical settings; however, these exclusion criteria were deemed necessary for this study because home-based care is not the standard of care in our setting (and thus deemed experimental by our IRB).

As part of our overall safety plan, we use the Standard Operating Procedure (SOP) for the Assessment and Management of Suicide and Homicide Risk in Active Duty Service Members that is used at MAMC [21]. This official SOP was updated during the course of our study, therefore we updated our procedures to remain consistent with the SOP. The SOP is based on information from several sources including the VA/DoD Clinical Practice Guidelines for Assessment and Management of Patients at Risk for Suicide [22], U.S. Air Force Guidelines for managing suicide behavior [23], and several other DoD policies and procedures. The same SOP guides assessments completed in-person or during telehealth sessions.

The SOP specifies a five-step process. Step one consists of a screen for the presence of suicidal, violent, or homicidal ideation, intent, or behavior. If the screen suggests presence of any risk, a full assessment interview is administered (step two) that assesses for frequency, intensity, and duration of ideation, content of thoughts and/or plans, impulsivity, history of suicidal and violent behavior, and other warning signs, risk, and protective factors. At the third step, clinicians integrate all information gathered from the assessment interview and compare that information to the SOP's guidelines in order to arrive at and document the current level of risk (i.e., not at elevated risk, low risk, intermediate risk, or high risk). The general descriptions of the levels of risk and associated clinical interventions specified in the SOP are shown in Table 2. In step four, clinicians are to document and provide rationale for the clinical responses provided. Finally, in step five of the risk assessment, clinicians develop and document safety plans with all patients with any elevation of risk. Safety plans can vary based on idiographic factors; however, the SOP encourages use of a safety plan to assist patients in identification of healthy coping strategies to be used when distressed, people to contact for additional support, ways to reduce risk in their environments (i.e., limiting substance use and restricting access to means), emergency/crisis response contact numbers, and making a commitment to living and to engage in treatment.

In our trial, the suicide risk assessment SOP is administered both at the intake/screening assessment and again during the first treatment session. It is also administered during subsequent assessment and/or treatment sessions as needed. That is, if a patient were to indicate a change in the severity or frequency of

Table 2. Determination of Suicide and Homicide Risk Level

Risk level	Criteria used to determine risk <sup>a</sup>	Clinical response <sup>b</sup>
Not at elevated risk	Denial of recent violent or suicidal ideation, intent, plans, or preparations. No history of violent behavior or suicide attempt in the previous 2 years.	No change necessary in routine outpatient clinical practice. Provide contact information for emergency responders. May consider devising safety plan for highly distressed patients.
Low risk	Endorsement of recent violent, homicidal, or suicidal ideation without intent to act or devise. Frequency and duration of ideation is low. No evidence of preparations or difficulty controlling impulses. No violent behavior or suicide attempt in the previous year.	Establish a safety plan with patient that addresses coping strategies, contact information for social supports, means restriction and limiting of substance use, and emergency contact information. Elicit a commitment to living and to engaging in treatment.
Intermediate risk	Endorsement of current homicidal or suicidal ideation without intent to act or difficulty controlling impulses. Frequency and duration of ideation is moderate to high. No recent violent behavior, suicide attempt, or preparations.	Take precautions of low risk and consider increasing frequency and/or intensity of contact to $\geq$ one time per week. Engage in peer consultation to share and track decision-making process and determine need for internal and external reporting/disclosures and means restrictions.
High risk	Endorsement of persistent homicidal or suicidal ideation with a plan or intent to act on a plan, and difficulty controlling impulses. Or, recent violent act, suicide attempt, or preparations.	Engage lower level precautions (including development of detailed safety plan with means restriction) and increase treatment intensity. Strongly consider implementing emergency response to arrange for safe transport of patient for evaluation and possible inpatient hospitalization. Initiate reporting/disclosure processes as indicated.

**Note:** The contents of this table are based on the MAMC risk assessment SOP [20].  
<sup>a</sup>In addition to these criteria, clinical judgment is used to integrate additional known risk factors (e.g., agitation, significant psychosocial stressors, hopelessness) and protective factors (e.g., interpersonal connections, help seeking, optimism) to ultimately arrive at and document a current risk-level determination. Further, if a patient has greater than one previous suicide attempt or violent act, risk level automatically advances at least one level. <sup>b</sup>These clinical responses reflect the minimum indicated response. Clinical judgment is always part of risk evaluation and clinicians may elect to engage a higher level of intervention if deemed appropriate.

suicidal ideation, the treatment provider would again assess for suicide risk per the SOP. If a patient is assessed to be at not elevated or low risk, s/he would not be assessed again until the final treatment session. Patients at or above intermediate risk are assessed during each treatment session until level of risk decreases below the intermediate risk threshold.

### **Patient Monitoring and Telehealth Session Checklist**

As part of the clinical assessment battery in our trial, patients are asked to complete the Beck Depression Inventory-II (BDI-II) [24] during the clinical outcomes assessments and to complete the Patient Health Questionnaire (nine item) [25] before each treatment session. During telehealth sessions, patients provide their responses to the self-report items verbally and the clinicians record the responses in the patient's treatment folder (clinical chart notes). These assessment measures provide a method for regular monitoring of clinical symptom levels and the presence of and/or change in suicide risk throughout treatment.

For all patients, regardless of their initial risk level determination, ideation and other signs of risk for suicide and violence are documented by study clinicians via a treatment session checklist. Our telehealth treatment session checklist was developed in part to provide clinicians with specific patient safety and suicide risk assessment, monitoring, and documentation procedures. The complete checklist used in the current study is published elsewhere [16]; however, its components and rationale are summarized as follows. The checklist begins with a verification of patient location and contact information. Prior to the first session, study clinicians obtain contact information for local emergency services based on patient's place of residence. Patients are also asked whether they feel that their home environment is safe and private. Additional questions assess whether the patient appeared intoxicated or otherwise disheveled, distressed, or upset; suicidal desire and ideation, such as whether the patient showed any signs of suicidal ideation or self-harm behavior; and plans and preparatory behavior, such as whether a weapon (firearm) was observed in the patient's home.

### **Risk Escalation and Continuity of Care Procedures**

For the purposes of our trial, if a study clinician observes a significant elevation in patient risk for suicide or violent behavior, the clinician is to immediately notify a supervisory psychologist who assists in determining what additional steps of the safety protocol are appropriate. Although determining the most appropriate clinical response for a given patient requires consideration of multiple factors, our safety protocol specifies minimum levels of intervention to be offered at each risk level. For example, at any time an assessment yields a risk level determination beyond no elevated risk, clinicians are expected to collaboratively develop a detailed safety plan with the patient, which may include identification of



safe coping strategies, working with the patient to remove lethal means (e.g., storing firearms in secured locations) and involving support persons with the plan.

While safety plans are familiar to many clinicians, providing patients with a copy of the plan during telepractice necessitates additional consideration. In our trial, telehealth patients are provided with blank copies of our safety plan at their in-person intake assessments so that the plans are available for use throughout treatment. In the event a telehealth patient does not have a blank copy of the safety plan, clinicians collaborate with the patients via telehealth in the drafting of a safety plan and then, once drafted, review the contents with the patient and allow the patient to indicate their comfort and agreement with the plan. Clinicians then mail a hard copy and/or scan and e-mail a copy of the plan to the patient. As with conventional in-office care, if a patient is assessed to be at high risk during a telehealth session, clinicians are expected to consider coordinating an evaluation of the patient for possible hospitalization. By gathering contact information for local emergency services and command, and identifying an emergency contact on behalf of the patient at the outset of telehealth services, our safety protocol is designed to enable clinicians to efficiently and effectively coordinate safe transport and evaluation of high risk patients.

We also have preplanned procedures in place to assure continuity of care for when patients complete treatment, are referred but do not enroll in treatment, or if they leave treatment early. To begin, we work with each patient to establish a continuity of care plan. This involves discussing with patients what may be the best options for them given their preferences and clinical needs. We also facilitate coordination with the initial referring care providers or other mental health professionals as appropriate. In addition, we provide all of our patients (regardless of risk level) with a list of local community mental health resources that they may keep as a reference. We follow-up with patients and/or the referring care providers when necessary and document as appropriate. Our continuity of care process helps to assure patient safety after they leave our care.

## SUMMARY

Our safety protocol and suicide risk assessment procedures include gathering patient information so that we can make informed risk assessments and enact indicated, effective responses to psychiatric emergencies. While the patients in our study may be at somewhat lower risk for suicide than other clinical patient populations because of our prescreening criteria, we have encountered patients ranging from low to high risk. The majority of our patients in the in-home treatment condition ( $n = 20$  at the time of this writing) began and ended treatment identified as “not at elevated risk” for suicide. The next most frequent risk category for our in-home patients has been low ( $n = 6$  at initial treatment session). In each of these cases, the patient endorsed a history of suicidal thinking with limited frequency, intensity, and duration, with no or limited plans and no

preparatory behavior, and few other risk factors identified. We have had three patients receiving care in the home who were identified as intermediate risk for suicide during their initial risk assessment. For each of these cases, the steps to take in the event of increased suicide risk were discussed with the patients. We have also experienced one case that escalated from “low” to “high risk” and one patient that was assessed to be “high risk” during our initial assessment. For both of these cases a “warm hand-off” was made to a supervisory clinician for further risk assessment. Given the high level of risk in these cases, the clinician discussed voluntary hospitalization with these patients and, on both occasions, the patients agreed that presenting to inpatient behavioral health for evaluation was the best option. Per U.S. Army regulations, the study staff contacted the Soldiers’ unit commanders and requested escorts to transport the patients to the ED. One evaluation resulted in inpatient admission; the other did not, although it did result in increased intensity of care. In all cases, we have successfully managed suicide risk by following pre-planned recommended procedures. Our work demonstrates that with appropriate planning and training, patient safety can be effectively managed during telepractice, even when patients are in settings that are not supervised by clinical staff (e.g., their own home).

One of the principal concerns regarding safety management during telehealth is how to effectively manage a suicidal patient when the telehealth connection is lost or disconnected during a clinical encounter. In our trial there have not been any situations where technology failures caused any difficulties with risk assessment, monitoring, or intervention procedures. However, consistent with practice recommendations and guidelines, we are careful to collect alternate methods of contact in case the videoconferencing connection is lost. We also identify a support person who can assist in an emergency. It is also important to tailor safety plans to the specific situations that may be encountered, particularly if patients are located in another geographical or jurisdictional area. Having knowledge of the requirements for civil commitment and *Tarasoff* type duty to warn/protect and incorporating these elements into your safety plan is essential. Even at a local level, simple safety procedures, such as what number to contact for emergency response services may vary based on geographic region.

Suicide risk assessment should be an ongoing process as risk levels are fluid and risk determination is based on integration of multiple pieces of information and clinical judgment [2, 26]. While assessment guidelines and checklists may enhance the standardization of the assessment process and reduce errors, suicide risk is conceptualized as existing along a continuum from no significant risk to imminent risk and it is the clinician who is ultimately charged with integrating present and historical information, considering the duration and severity of explicit and implicit risk factors, and differentially weighting risk and protective factors to arrive at a clinical determination [2, 26]. Maintaining a comprehensive risk management or safety protocol that guides the assessment process, encourages consultation with colleagues and supervisors, and informs clinical

decision making can reduce patient and clinician anxiety, enhance accuracy and reliability of the assessment, and thereby, supports patient safety [27].

Safety planning with patients during telepractice may also carry additional clinical benefits [28]. For example, the process of working collaboratively with patients to establish a safety plan for telehealth encounters may provide the patient with increased confidence and therefore contribute to improved comfort and acceptance of the treatment process. Discussion of technical procedures as well as initial testing of telehealth equipment may also help to facilitate a collaborative therapeutic relationship. In some cases, the involvement of a family member or other supportive person during technical set-up and as part of safety planning may help facilitate patient support and overall treatment adherence. Of course, it is necessary to consider the preferences of patients, their autonomy, and privacy risks when involving others in their care. Telehealth capabilities also provide increased access to care, especially for patients who reside in remote or underserved areas. For these patients, access to care via telehealth services may be critical for ongoing treatment of suicidality, including assessment, intervention, medication management, and follow-up care.

In conclusion, telehealth is a growing area of practice that provides opportunities to increase access to care, improve convenience, and expand the range of clinical services. The effective assessment and management of patients experiencing a psychiatric crisis raises important legal, operational, and clinical issues that telepractitioners must be cognizant of. These issues, however, should not dissuade practitioners from clinical telepractice. With appropriate safety planning, training, and familiarity with published guidelines, telepractice is as feasible as traditional in-office clinical care delivery.

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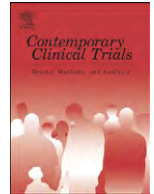
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# Design and methodology of a randomized clinical trial of home-based telemental health treatment for U.S. military personnel and veterans with depression<sup>☆</sup>

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## ABSTRACT

Home-based telemental health (TMH) treatments have the potential to address current and future health needs of military service members, veterans, and their families, especially for those who live in rural or underserved areas. The use of home-based TMH treatments to address the behavioral health care needs of U.S. military healthcare beneficiaries is not presently considered standard of care in the Military Health System. The feasibility, safety, and clinical efficacy of home-based TMH treatments must be established before broad dissemination of home-based treatment programs can be implemented. This paper describes the design, methodology, and protocol of a clinical trial that compares in-office to home-based Behavioral Activation for Depression (BATD) treatment delivered via web-based video technology for service members and veterans with depression. This grant funded three-year randomized clinical trial is being conducted at the National Center for Telehealth and Technology at Joint-base Lewis-McChord and at the Portland VA Medical Center. Best practice recommendations regarding the implementation of in-home telehealth in the military setting as well as the cultural and contextual factors of providing in-home care to active duty and veteran military populations are also discussed.

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## 1. Introduction

There is mounting evidence supporting the clinical effectiveness of telemental health (TMH) treatments [31,33] as well as patient and provider satisfaction with TMH [5,35]. The

evidence base supporting home-based telemental health (HBTMH) is also growing, and HBTMH services are expanding across diverse care settings including the VA Health Care System [11]. HBTMH treatment options have multiple benefits: they can improve access to care services, reduce the burden of travel expenses, eliminate wait times, and reduce time away from work to attend appointments. Stigma associated with mental health conditions is another barrier to care that may influence willingness to seek mental health treatment. The option to receive care in the comfort and privacy of the home is one way to combat this problem [40].

Mental health treatments provided directly to the homes of U.S. military personnel are not presently the standard of

<sup>☆</sup> DISCLAIMER: The views expressed are those of the authors and do not reflect the official policy or position of the Department of Defense of the U.S. Government.

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care in the Military Health System (MHS). Clinical research is needed to test the feasibility, safety, and effectiveness of HBTMH treatments in the military setting in order to inform policies regarding the adoption and expansion of HBTMH. To address this need, we are conducting a randomized clinical trial (RCT) that compares Behavioral Activation Treatment for Depression (BATD; [14]) delivered in-office to BATD delivered via webcams to the homes of U.S. military service members and veterans with depression.

Behavioral Activation for depression was selected as the treatment in our trial for several reasons. First, military personnel may be highly agreeable to BA as a treatment option. Behavioral Activation is based on a behavioral conceptualization of depression which posits that depression is an understandable response to negative life events and difficult environments [13]. This stance, that “depression makes sense,” renders BA less stigmatizing than other treatments because it does not assume weakness or disorder on the part of the patient [37]. Behavioral Activation is also an action-oriented treatment that may be particularly acceptable to physically active military service members. Second, BA has considerable empirical support for the treatment of depression among both civilians (see [13]) and Veteran populations [7] as well preliminary support as a treatment for PTSD [12,20]. Third, depression is a highly prevalent mental health condition in both the military and Veterans populations and it is the most frequent reason for psychiatric hospitalization in both the active and reserve components of the U.S. Armed Forces [27].

With this paper we describe the design, methodology, safety management, and treatment protocols for an in-progress Military Operational Medicine and Research Programs (MOMRP) grant funded multi-site clinical trial of HBTMH treatment. The trial is registered on the United States National Institutes of Health Clinical Trials Registry, (ClinicalTrials.gov Identifier #NCT01599585) available online at: <http://clinicaltrials.gov/show/NCT01599585>. In addition to testing the effectiveness of a HBTMH treatment, the study provides data on patient satisfaction with a home-based care and it advances the knowledge base regarding the safety and risk management procedures of home-based treatments in both the military and VA settings. The study also tests the feasibility of readily available synchronous videoconferencing technologies (i.e., webcams and laptop computers) to provide care to military personnel and veterans in the home. This paper should be particularly useful to researchers who are interested in the technical aspects of implementing clinical telehealth research in the military, VA, and other health care settings. The paper also highlights the procedures for applying a two-group non-inferiority trial design to establish a novel or alternative mode of treatment delivery as standard of care.

## 2. Research design and methods

### 2.1. Study design

This RCT is a two-group non-inferiority design that compares the effectiveness of BATD delivered via web-camera to standard in-office BATD. The study is being conducted at the National Center for Telehealth and Technology (T2) located at Joint Base Lewis-McChord (JBLM; Fort Lewis, WA) and at the Portland Veterans Administration Medical Center (PVA;

Portland, OR). We followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines in developing the protocol, and our procedures adhere to the principles and recommendations of the World Medical Association, Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects, as well as all applicable Codes of Federal Regulation and Department of Army Regulations. The research protocols were approved by the Institutional Review Board (IRB) at each site and the protocols underwent separate review processes by the Army Human Research Protection Office (HRPO).

The study's conceptual design is shown in Fig. 1. Eligible patients have an equal chance of being randomized to either the in-office or in-home treatment groups. All patients are provided with 8 sessions of BATD that is guided by a treatment protocol manual. Patients in both intervention groups follow the same assessment schedule with assessments at baseline, mid-treatment, 1 week post-treatment, and 3 months post treatment (see Table 1). Treatment clinicians are blinded to clinical assessment results. This design characteristic, along with the treatment fidelity process (described in Section 2.5), was implemented to prevent the study clinicians from systematically altering treatment delivery due to potential biases in favor of or against either diagnostic group.

### 2.2. Setting

Joint Base Lewis-McChord (JBLM) is a large U.S. Army and U.S. Air Force base that is home to Madigan Army Medical Center (MAMC), a Regional Medical Center and teaching hospital that serves more than 108,000 beneficiaries across a network of military treatment facilities located throughout Washington State, Oregon, and California. The

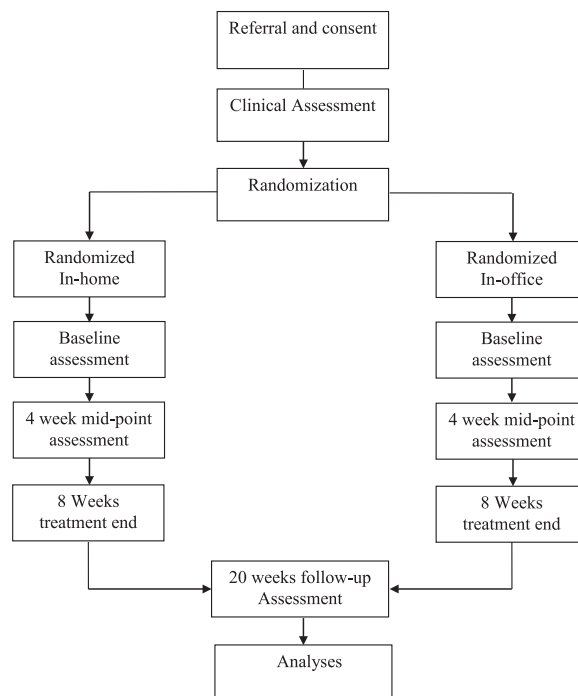


Fig. 1. Study flow chart.

**Table 1**

Schedule of measures and survey instruments.

Measure	Initial	Baseline			Midpoint				Post-Tx	3-month follow-up
		Wk 1	Wk 2	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8	Final
SCID-I/P	X				X				X	X
BDI-II	X				X				X	X
BHS	X				X				X	X
BAI	X				X				X	X
LS	X				X				X	X
PCL-M	X				X				X	X
IASMHS	X								X	X
Safety Measures		X	X	X	X	X	X	X	X	X
CSQ										X
Technology Questionnaire	X								X	

Note. SCID-I/P = Structured Clinical Interview for the DSM-IV Axis I Disorders, Research Version, Patient Edition; BHS = Beck Hopelessness Scale; BDI-II = Beck Depression Inventory-II; BAI = Beck Anxiety Inventory; LS = Loneliness Scale; PCL-M = PTSD Checklist – Military; IASMHS = Inventory of Attitudes Toward Seeking Mental Health Services; CSQ = Client Satisfaction Questionnaire; Technology Questionnaire = Computer and Audiovisual Technology Questionnaire.

National Center for Telehealth & Technology is part of the Defense Centers of Excellence for Psychological Health & Traumatic Brain Injury and the Military Health System (MHS). It is co-located with MAMC on JBLM. The National Center for Telehealth & Technology's mission is to lead in the development and research of telehealth and health technology solutions for the military community. Study patients at T2 are comprised of active-duty, reserve, and National Guard service members who are eligible to receive health care through the MHS. The study patients at the PVA site are military veterans receiving health care services through the VA hospital in central Portland (Veterans Integrated Service Network [VISN] 20). These veterans reside throughout various towns and cities in Northwest Oregon and Southwest Washington State. The study teams at each site meet every two weeks via videoconferencing to assure parallel operations and assess study progress.

### 2.3. Participants and enrollment methods

Approximately 120 ( $n = 90$  at JBLM;  $n = 30$  at PVA) patients will be recruited with an anticipated treatment completion rate of 108 (90%; 54 per treatment group). Patients are male and female members of the U.S. Armed Forces recruited from MAMC and the larger JBLM community as well as U.S. military veterans recruited at the PVA site. Study eligibility depends in part on whether the patient has high speed internet access at home (384kbs or greater) as well as a private space for treatment sessions (complete inclusion and exclusion criteria can be found in Table 2). Patients that are randomized to the in-office treatment group are seen in a traditional face-to-face clinical office setting at T2 or PVA. Patients assigned to the in-home treatment group are issued a Dell Precision M6500 laptop computer, Tandberg Precision High Definition webcam, and auxiliary equipment (e.g. mouse, charging station and power cables) that they connect to their own private internet access (either wireless or wired connection). The lap-tops are password protected and functionality is restricted so that unauthorized software cannot be loaded onto them. The videoconferencing software being used is Cisco Jabber Video for Telepresence. This software has embedded encryption features that meet Health Insurance

Portability and Accountability Act requirements and it is authorized for use by the U.S. Army.

The primary referral sources for study patients are clinical providers within behavioral health, primary care, and operational medicine service programs at JBLM and PVA (e.g., psychologists, psychiatrists, physicians, social workers, nurse practitioners, and nurses). Military chaplains on JBLM also serve as a recruitment source. These referring professionals are not affiliated with the trial, but have been informed about referral procedures during informational presentations by study staff. Additional recruitment strategies include flyers and banners as well as the use of social media campaigns (i.e. Facebook, Twitter, and LinkedIn) that target treatment providers who could make patient referrals. Patient recruitment began in August of 2012.

Following referral, the study coordinator conducts a brief phone screen and schedules each potential patient for an individual meeting with an outcomes assessor to complete the informed consent process and discuss study procedures in detail. Participation is discussed as entirely voluntary without negative consequences for withdrawal. At the PVA site, patients receive \$20 for each of the first three assessment visits, and \$40 for completion of the 3 month follow-up assessment. Patients at the JBLM site cannot be compensated for their time per US Army regulations. Each patient's capacity to consent and answer any questions about study procedures is monitored during the course of treatment and during assessment visits as well.

After patients complete the baseline assessment (see Section 2.7), those meeting eligibility criteria are assigned to treatment condition by the study coordinator (who is not blinded to condition) according to the pre-determined randomization schedule. The treatment condition is determined for both sites by using a computer generated table with a block ( $n = 10$ ) randomization algorithm. This procedure allows each patient to have equal chance of being assigned to either of the two groups while assuring equal distribution of patients to the two conditions over the course of the study. We did not use a stratification scheme based on site, demographic variables, or medication status. We anticipate that demographic characteristics, such as gender, race, and age will be reflective of the military and veteran population from which we are



**Table 2**

Inclusion and exclusion criteria for patient enrollment.

Inclusion criteria
(a) Met diagnostic criteria for minor depressive disorder or major depressive disorder, as determined by the SCID-I/P
(b) High speed internet access at home (384 kbs minimum)
(c) If taking psychoactive medications, has maintained a stable regimen for a minimum of 30 days prior to study entry
(d) Informed consent read and signed
Exclusion criteria
(a) Currently undergoing psychotherapy for depression
(b) <18 or >65 years of age
(c) Active psychotic symptoms/disorder as determined by the SCID-I/P
(d) Dysthymic disorder as determined by the SCID-I/P
(e) Current suicidal ideation with intent or recent (within six months) history of a suicide attempt
(f) History of organic mental disorder
(g) Current substance dependence as determined by the SCID-I/P (lifetime substance dependence or substance abuse will not be excluded)
(h) History of violence or poor impulse control
(i) Significant ongoing stressors that require urgent crisis intervention
(j) Have a living arrangement that will not permit the use of a private space to participate in the study

sampling. These variables will be treated as covariates in our analyses (See [Section 2.10](#)). We will examine potential differences in medication use between groups in post-hoc analyses.

#### 2.4. Clinician preparation and training

Assessments are conducted by outcomes assessors that have been blinded to treatment condition. Assessors are eligible to meet with patients after completing specific assessment training protocols (i.e., literature review, assessment training videos, DSM-IV TR review, taped practice sessions with expert review, and role plays). Study clinicians are credentialed healthcare providers at MAMC or PVA. All study clinicians are doctoral level clinical psychologists who have completed specific training requirements for both BATD as well as use of the TMH technology and equipment. BATD training consists of an extensive literature review (both theoretical and empirical), completion of mock sessions, and attendance at a two day intensive training workshop led by Dr. Ron Acierno, Ph.D. who is one of the authors of the BATD protocol. Training in TMH technology and equipment consists of test calls, troubleshooting practice, and equipment manual review. All training requirements are completed before a provider is allowed to actively treat study patients.

#### 2.5. Behavioral Activation treatment protocol

BATD and other Behavioral Activation protocols originated from behavior analytic models of classical and operant conditioning [25,30,36] and the behavioral component of cognitive therapy for depression [1,15–17]. Behavior analytic theory posits that depression develops when learned behavioral contingencies fail to produce stable, diverse, and reinforcing environmental consequences [13]. This can occur in a wide range of contexts (e.g., trauma, loss, daily stressors) and is likely modulated by biological predispositions. When an individual's behavior no longer produces reinforcing consequences, a reduction in the frequency of the target behavior

occurs. Often, this can occur in parallel with an increase in the frequency of other maladaptive behaviors associated with that response, including withdrawal, negative internal affective experiences, and ultimately, symptoms of depression. BATD aims to reengage depressed individuals in their lives through focused, values-based activation strategies. These strategies counter patterns of negative affect, withdrawal, and inactivity by reestablishing contact with naturally reinforcing consequences for adaptive behavior that alleviates depressed mood and creates stable patterns for accessing reinforcing consequences.

The BATD treatment protocol used in the present trial is based on a revised BATD treatment manual by Lejuez et al. [14]. The protocol prescribes 8-sessions of BATD that can be delivered either in-person or by VCT. In the first session, patients are provided with psychoeducation about depression and introduced to the treatment rationale and the role and importance of daily monitoring for the duration of the treatment. In the second session, previous content is reviewed, followed by introductions to the concepts of values and activity planning. With regards to values, clinicians utilize a series of prompts and writing tasks to encourage patients to identify their personal values within five different major life domains (i.e., relationships, education/career, recreation/interests, mind/body/spirituality, and daily responsibilities). Values are defined as ongoing, meaningful patterns of action and are contrasted with goals, which have an endpoint. Patients then collaborate with clinicians to devise lists of activities that exemplify their values. For example, if a patient values spending quality time with his children, specific activities might include taking them to the park for a game of 'catch,' reading 3 short bedtime stories to them each night, and spending half of a hour helping them to complete homework at approximately 6:00 pm each day. Activity planning is the process of collaboratively scheduling these activities in advance in order to maximize the potential for contact with naturally occurring reinforcement in a patient's day-to-day life. In sessions three through eight, the treatment rationale is continuously reviewed, and patients are asked to schedule more and varied values-consistent activities using a daily planner of their choice (planners are provided for use with treatment, but patients are encouraged to utilize established planners or scheduling systems [e.g., their smartphone] to increase the chances of regular use). Final sessions are also used to address issues related to termination, treatment progress, and ways to use what has been learned in treatment for relapse prevention.

The present study's treatment protocol also contains specific provisions for VCT-based treatment delivery such as equipment set-up, procedures for initiating the VCT sessions, and steps to take in the event of disrupted service. All clinical procedures for the in-office and in-home conditions are identical.

#### 2.6. Treatment fidelity

To assure adherence to the treatment protocol, treatment providers complete session-by-session "Adherence Checklists" that highlight the key elements of each session as well as homework that is assigned. Treatment providers also participate in weekly individual and group supervision and they attend weekly cross-site (i.e., JBLM and PVA) case consultation

meetings. To assess adherence to the treatment protocol, all treatment sessions are digitally recorded. Sessions at MAMC are video recorded onto DVD (although the video captures the clinician only along with audio for both clinician and patient), whereas sessions at PVA are audio recorded only (per VA policy). Ten percent of these session recordings are randomly selected and sent to an expert fidelity reviewer on a monthly basis (Dr. Ron Acierno). The fidelity reviewer was selected for his expertise in the delivery of BATD to service members and veterans via telehealth. The reviewer codes each session recording for compliance based on a treatment fidelity checklist delineating the essential therapeutic components that must be delivered in each session of BATD.

Description of the recordings and fidelity review is provided in the informed consent process at both study sites. VA study clinicians are also required to obtain patient consent for recording using the VA Form 10-3203, "Consent for use of picture and/or voice" in addition to their IRB approved Informed Consent Form. At JBLM, the digital recordings are retained for 5 years after the publication of results. At PVAMC, in accordance with VA policy, digital recordings are retained indefinitely.

### 2.7. Safety management protocol

During the baseline assessment, outcomes assessors conduct a thorough suicide risk assessment to determine level of risk per MAMC standard operating procedure (see [20] for further description). Level of risk depends on a combination of risk correlates (e.g., substance abuse, significant psychosocial stressors); factors related to suicide desire and ideation (e.g., articulated reasons for living, passive thoughts of attempt); and resolved plans and preparation (e.g., available means, specific plans). Patients are asked to identify a third party (e.g., family member or friend) who may be able to assist in cases of emergency or imminent risk. At JBLM, service members are also asked to provide the contact information for their immediate commanding officers in case of emergency or elevated risk necessitating command notification, per Army regulation. This additional exception to confidentiality in the military setting is thoroughly reviewed as part of informed consent. Lastly, for patients randomized to the in-home condition, clinicians identify the best contact information for law enforcement and emergency services nearest each patient's home address for use in case of emergency.

Suicidal risk is re-assessed during the first treatment session (using the same standard operating procedure described above). The assessment is also conducted during subsequent assessment and/or treatment sessions for patients identified to be at intermediate or high risk or if a patient indicates a change in the severity or frequency of suicidal ideation. Individuals advance from low to higher levels of risk based on frequency, intensity, and duration of ideation, as well as presence of intent and/or plan or evaluation of risk factors. For all patients, regardless of their initial risk level determination, ideation and other signs of risk for self-harm are also monitored at each session by means of a treatment session checklist developed specifically for this study (see [Attachment 1](#)). Relevant questions assess correlates of safety risk, alcohol or substance use, appearance of being disoriented or upset; reports of suicidal

desire and ideation, and whether a weapon was observed. This checklist also includes questions that assess aspects of patient safety other than suicide risk. For example, some questions assess more general safety-related questions, such as, "Is anyone else at home today?", whereas some questions are more specific, such as "Did the patient indicate intent to harm others?" Finally, in line with Luxton and colleagues' [18] definition of safety, this checklist also addresses matters of privacy and confidentiality (e.g., "Do you feel that your environment is safe and private?"), as well as technology, equipment and connectivity (e.g., "What number can I reach you at if we get disconnected?", "Were there problems initiating/maintaining the webcam connection?"). The checklist also contains space for clinician comments.

If any study clinician or assessor becomes aware of any elevation in patient risk for suicide or violent behavior, established written safety protocols are followed according to the regulations of the site responsible for that patient. This may include developing a detailed safety plan with patients, modifying risk factors and removing lethal means for suicide or violent behavior, involving the third party identified by patients to help with enacting the safety plan, modifying risk factors, assisting with patient safety until the patient is transferred to emergency services, involving the patient's commander and assigned unit, and transferring the patient to inpatient care. At the baseline assessment, high short term risk for suicide behavior would preclude participation in the study in favor of more acute, crisis-focused care. Elevated risk during treatment is managed via consultation by the treatment team, who collectively determine whether the patient in question can be safely and effectively treated within the confines of the treatment protocol or whether more acute and/or intensive care is warranted. For participants who are determined to be in the "high risk" category on the suicide assessment but are not presently experiencing a crisis, the treatment provider works to establish a safety plan with the participant while coordinating the transfer of the participant out of the study and to appropriate care services. Additional information regarding suicide risk management and assessment procedures used in the present trial are described by Luxton, O'Brien, Pruitt, Johnson, & Kramer (In Press).

All assessors and providers adhere to Federal Health Insurance Portability and Accountability Act regulations as well as their state (Washington/Oregon) and military/VA requirements of confidentiality, including exceptions and reporting of imminent risk of harm to self or others, including harm to vulnerable populations. The staff at T2 also complies with Army Medical Command (MEDCOM) regulations mandating that providers in the Military Health System must follow additional mandatory reporting requirements pertaining to substance use, sexual assault, and domestic violence which may necessitate notification of an individual's unit commander.

### 2.8. Assessments and measures

After obtaining informed consent, the condition naïve outcomes assessor determines each person's study eligibility by asking a series of questions related to inclusion and exclusion criteria and conducts an abbreviated Structured Clinical Interview for the DSM-IV Axis I Disorders, Research Version, Patient Edition (SCID-I/P; [8]) which focuses on the mood, psychotic,

and substance use disorder sections. If eligible for participation, a demographics questionnaire is administered along with a set of self-report questionnaires which follow the assessment schedule outlined in Table 2. These self-report measures include: Beck

Depression Inventory-II (BDI-II; [3]), Beck Hopelessness Scale (BHS; [4]), Beck Anxiety Inventory (BAI; [2]), Loneliness Scale (LS; [6]), PTSD Checklist – Military (PCL-M; [38]), Inventory of Attitudes Toward Seeking Mental Health Services (IASMHS;

#### Attachment 1

Home-based telemental health treatment session checklist.

### Treatment Session Checklist

Participant ID: \_\_\_\_\_ Clinician: \_\_\_\_\_ Session Date: \_\_\_\_\_ Session #: \_\_\_\_\_

<p><b>Questions to be asked at beginning of session (in-home telehealth condition only)</b></p> <p>1. Is anyone else at home today YES NO (circle one) a. If yes, who? _____</p> <p>2. Do you anticipate any disruptions during our session today? YES NO (circle one) a. If yes, explain: _____</p> <p>3. Do you feel that your environment is safe and private? YES NO (circle one) a. If yes, explain: _____</p> <p>4. What number can I reach you at if we get disconnected? _____</p> <p><b>Participant</b></p> <p>1. Was participant late to the session? YES NO (circle one) a. If yes, how many minutes late? _____</p> <p>2. Did the participant cancel session early? YES NO (circle one) a. If yes, explain: _____</p> <p>3. Was the session rescheduled? YES NO (circle one) a. If yes, who was it rescheduled by? _____</p> <p>4. Did the participant miss the session without giving prior notice? YES NO (circle one) a. If yes, explain: _____</p> <p>5. Did the participant appear disheveled? N/A YES NO (circle one) 1. If yes, explain: _____</p> <p>6. Did participant appear intoxicated? N/A YES NO (circle one) 1. If yes, explain: _____</p> <p>7. Did patient show any signs of suicidal ideation? YES NO (circle one) 1. If yes, explain: _____</p> <p>8. Did patient exhibit self-harm behavior during session? YES NO (circle one) 1. If yes, explain: _____</p> <p>9. Was there a suicide attempt since last session? YES NO (circle one) 1. If yes, explain: _____</p> <p>10. Did patient indicate intent to harm to others? YES NO (circle one) 1. If yes, explain: _____</p>
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<p>11. Did participant become upset/distressed during session? YES NO (circle one)</p> <p>1. If yes, explain: _____</p>
<p><b>Safety Protocol</b></p> <p>1. Was the safety protocol initiated? YES NO (circle one)</p> <p>2. Was it necessary to contact collateral? YES NO (circle one)</p> <p>a. If yes, check all that apply:</p> <p><input type="checkbox"/> Able to contact the collateral</p> <p><input type="checkbox"/> Collateral responded to issue</p> <p><input type="checkbox"/> The collateral was helpful</p> <p>3. Was the police non-emergency line or 911 called? YES NO (circle one)</p> <p>a. If yes, check all that apply:</p> <p><input type="checkbox"/> The agency initiated an emergency response</p> <p><input type="checkbox"/> The agency chose not to provide an emergency response</p> <p><input type="checkbox"/> The agency was unable to provide an immediately emergency response (e.g., location)</p> <p>4. Was a supervisor notified or consulted? YES NO (circle one)</p> <p>a. If yes,</p> <p>i. Name of supervisor: _____</p> <p>ii. Date and time contacted: _____</p>
<p><b>Environment (in-home telehealth condition only)</b></p> <p>1. Were there distractions at the patient's location (e.g., pets, children, cell phones)? YES NO (circle one)</p> <p>a. If yes, explain: _____</p> <p>b. If yes, was this useful clinical information? YES NO (circle one)</p> <p>2. Was the session interrupted by another person? YES NO (circle one)</p> <p>a. If yes, explain: _____</p> <p>b. If yes, was this useful clinical information? YES NO (circle one)</p> <p>3. Any weapons observed during session? YES NO (circle one)</p> <p>a. If yes, explain: _____</p> <p>b. If yes, was this useful clinical information? YES NO (circle one)</p> <p>4. Did the participant's room have adequate lighting? YES NO (circle one)</p> <p>a. If yes, explain: _____</p>
<p><b>Technology Issues (in-home telehealth condition only)</b></p> <p>1. Were there problems <i>initiating</i> the webcam connection? YES NO (circle one)</p> <p>a. If yes, how many minutes until connection made? _____</p> <p>b. Indicate source of problem (check all that apply)</p> <p><input type="checkbox"/> Internet Connection (ISP Problem)</p>

[21]), Client Satisfaction Questionnaire (CSQ; [27]), Computer and Audiovisual Technology Questionnaire (Technology Questionnaire; adapted by study authors from [7]), and safety measures (recording any clinical safety concerns and adverse events at each client contact). Additionally, a comprehensive suicide risk assessment is conducted at the initial meeting by the

study assessor with ongoing monitoring by study therapists as part of clinical risk management (see Section 2.10).

All standardized symptom inventory scales have been previously used in research with military populations and demonstrate adequate psychometric properties (e.g., validity and internal consistency reliability estimates calculated in

<input type="checkbox"/> Software problem <input type="checkbox"/> Hardware problem (PC, webcam, microphone) <input type="checkbox"/> Unable to establish webcam connection <input type="checkbox"/> Unable to follow-up via telephone <input type="checkbox"/> Unable to contact the PSP Describe: _____ _____
2. Were there problems <b><i>maintaining</i></b> the webcam connection? YES NO ( <i>circle one</i> ) a. <i>If yes, how many minutes until connection made?</i> _____ b. <i>Indicate source of problem (check all that apply)</i> <input type="checkbox"/> Internet Connection (ISP Problem) <input type="checkbox"/> Software problem <input type="checkbox"/> Hardware problem (PC, webcam, microphone) <input type="checkbox"/> Participant purposely terminated contact <input type="checkbox"/> Unable to re-establish webcam connection <input type="checkbox"/> Unable to follow-up via telephone <input type="checkbox"/> Unable to contact the PSP Describe: _____ _____
3. Was it necessary to contact participant by phone? YES NO ( <i>circle one</i> )
<b>Other Information:</b> _____ _____ _____ _____

data collected from samples with similar demographic profiles). Research on the Loneliness Scale has demonstrated sound psychometric outcomes in a large sample of adults [6], and Mackenzie et al. [21] presented initial validity evidence for the IASMHS with strong psychometrics calculated from a sample of young adult, undergraduate students. Given the frequent movement of military personnel between installations in the United States as well as deployment to overseas locations, the study procedures allow for the three month follow-up assessment to be completed remotely if necessary via a combination of telephone interview (SCID) and mail (self-report questionnaires).

The outcome assessors remain blinded to treatment condition throughout the course of the study to avoid bias the assessor may have toward any one particular treatment condition. Procedural and physical barriers are used to protect the assessor from being inadvertently exposed to information about the treatment condition to which patients have been assigned. For example, treatment and assessment sessions take place in different office spaces and efforts are taken to avoid scheduling both types of sessions at the same time. Assessors do not participate in regularly scheduled supervision and consultation of clinical cases, and are selectively excluded from administrative meetings in which discussion of the treatment process might occur. The greatest risk to these barriers is the patient revealing the method of treatment delivery to the assessor at one of the

non-baseline assessments. As such, instructions are provided to the patient at the outset of each assessment to avoid inadvertently revealing condition assignment. If a patient's treatment condition is inadvertently revealed to an outcomes assessor, the assessor documents the occurrence in an assessment disposition note to allow for post-hoc analysis.

## 2.9. Outcomes

The primary outcome variables (continuous measures) are depressive symptoms measured by the BDI-II and hopelessness measured by the BHS. We are also monitoring patient safety during study participation in order to establish evidence for the safe use of HBTMH. Study clinicians document safety concerns and record any adverse safety events during the course of treatment on the Treatment Session Checklist. Additional analyses will assess treatment group differences in anxiety (BAI) and PTSD (PCL-M) symptoms, patient satisfaction with and attitudes toward treatment (CSQ, IASMHS), quality of life (LS), and healthcare utilization.

## 2.10. Statistical methods

We are using a non-inferiority design for this study because we expect the observed efficacy of the in-home



BATD intervention will be no worse than that observed for in-person BATD. Non-inferiority models can be considered “a one-sided test used to determine if a novel intervention is no worse than a standard intervention” ([10], p. 434). The non-inferiority design is especially useful for comparing interventions that have been modified or adapted for different modes of delivery to treatment as usual [10]. Non-inferiority trials have also been previously used to compare telehealth interventions to conventional in-person care (e.g., [7,23,29]). Our study will test the primary null hypothesis that differences between group outcome measures for patients in the VCT-based BATD condition and those from the in-person BATD condition will be greater than a set threshold or margin (labeled  $\Delta$ ). The null hypothesis will be rejected and thus the VCT treatment considered non-inferior to standard in-person treatment if the confidence interval calculated around the treatment difference falls within the established  $\Delta$ .

#### 2.10.1. Power analysis

We first determined the non-inferiority margin based on methodology used in similar studies as well as clinical considerations [10,28]. A 0.5 standard deviation change in scores has been used in clinical treatment research as an indicator of clinically significant improvement (e.g., [32,34]). This margin is consistent with clinically significant change in BDI-II total scores and standard deviations of approximately 10 points in both military [39] and civilian [9] samples. From a clinical standpoint, it is reasonable to consider a 5 or fewer point change in BDI-II scores as clinically unimportant, which also aligns with the 0.5 standard deviation criteria for significant change used in previous research. Thus, we set our non-inferiority margin at 0.5 SD and used a 2-sided test with a 90% CI following Mohr et al.'s [22] approach. Power analyses following a standardized method (variance of 1) based on these parameters (Cohen's  $d$  of 0.5) yielded a minimum sample size of 49 patients in each treatment group to adequately power our non-inferiority analyses assuming an observed difference of 0 in the mean efficacy between the two study groups. Thus, we targeted our sample size for 120 assuming a 10% rate of drop-out. Although we will pool data from the two participating sites for analyses, the sample sizes are adequate to assess any potential differences in demographics and clinical characteristics between the two sites.

#### 2.10.2. Multilevel model

We plan to follow the methodology of previous non-inferiority studies (i.e., [7,22,24]) by using a confidence interval method for evaluating the difference between treatment groups and pairing this approach with an intent-to-treat (ITT) analysis. We will test the primary null hypothesis that differences in outcome measure scores between the two conditions (in-home vs. in-office BATD) at the post assessment time point will be greater than the set clinically relevant threshold or margin using a multilevel (also referred to as *hierarchical* or *random effects*) modeling approach. The primary outcome measure is BDI-II score and secondary analyses will include the BHS. We will include both individual and sessions as units of the analysis with patients nested within sessions. The baseline values for the outcome measures will be accounted for in the model. The null hypothesis will be rejected if the upper limit of the CI calculated around the difference in BDI-II scores between the two groups falls below the established margin,

suggesting that the VCT treatment can be considered non-inferior to standard in-person treatment.

#### 2.10.3. Safety and feasibility

Safety will primarily be evaluated by examining the rates of safety events (e.g., activation of the safety management protocol because of elevated suicide risk, etc.) during the course of treatment. Feasibility will be assessed by examining the frequency and types of technical issues that occur during the course of treatment. Patient drop-out rates, levels of patient treatment satisfaction and attitudes toward treatment will also be compared between the treatment conditions to help evaluate feasibility of HBTMH.

### 3. Discussion

With this paper we have presented the design, methodology, and protocol of a clinical trial that compares in-office to home-based Behavioral Activation for Depression (BATD) treatment delivered via web-based video technology for service members and veterans with depression. Recruitment and assessment phases for the trial are underway and are planned to be completed by the end of 2014. This trial is expected to yield important data that can help guide the development of treatment guidelines and standards of care (e.g., within the Department of Defense and the Veterans Administration) that aim to improve access to quality care for military service members and veterans. This trial will also demonstrate the limitations of home-based TMH care thereby allowing for further refinement of safety and technical procedures to maximize effectiveness and safety of this modality of care.

This study is generating important information about challenges and best practices when conducting research with active duty military service members and home-based TMH. Additional steps must be taken to meet requirements of multiple review boards and oversight committees, which may take more time and resources than is typically necessary for doing similar research in non-military settings. There is additional oversight regarding reporting of adverse events, verifying provider credentials, and accessing equipment, computing, and communications systems within the military. Further, patient recruitment strategies must be sensitive to varying perceptions regarding stigma associated with mental health treatment and clinical research within the military culture and community. Retention efforts must be flexible in order to accommodate the high mobility of the military population given the potential for relocation and deployment. In this study, accommodations have been made to conduct follow-up assessments over the telephone since it is expected that some patients may have relocated (due to military assignment or discharge from service) during the period between completing treatment and the 3-month follow-up assessment. We hope that our methods presented here, and our future trial results, will help to guide additional research regarding home-based TMH treatments in the military and VA settings.

Factors associated with an active-duty military population also impact clinical practices and feasibility of home-based treatments in the MHS. Working within this system, clinicians must consider specific rules regarding the protection of privacy and confidentiality that may be different than what is encountered in civilian care settings. For example, military unit commanders are authorized to verify treatment

attendance of their subordinates and clinicians must comply with requirements for mandated reporting to unit chain of command that would exceed most state laws (e.g., all active substance abuse, any suspected incidence of domestic violence). Also, the process of patient safety (e.g., suicide risk assessment) must be adapted, as we have done, to fit local requirements.

We are also collecting treatment adherence data with our trial that will help us to determine what factors including scheduling may influence treatment outcomes. To date, we have been successful in working with patients to schedule treatment sessions during day-time hours. While home-based options may be ideally suited for patients who are already at home (due to medical leave, unemployment, etc.), we are finding that home-based options are feasible in the military setting when sessions are scheduled in the morning before work or at the end of the day. In addition to being convenient for patients, time away from work and travel costs can be minimized because the service member does not have to leave work for a session at a clinic and then return back to work. Home-based TMH care may thus be an ideal solution for when travel to a military treatment facility or clinic is not feasible or if there is limited clinical space near where the patient works (i.e., in remote areas).

In conclusion, home-based mental health services have the potential to provide effective treatment to the many individuals who may not otherwise pursue mental health care, either due to logistical barriers or perceived stigma of receiving care. Home-based treatment options may be particularly useful in addressing the aforementioned barriers to care and can augment current treatment services provided in the MHS and VAHCS. The results of this clinical trial will provide basic information that is needed to inform policy decisions regarding the implementation of home-based behavioral health care in the U.S. military and further expansion in other settings including the VA Health System.

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